UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *Plaintiff-Intervenor*, v. STEWARD HEALTH CARE SYSTEM LLC; STEWARD MEDICAL GROUP, INC.; and STEWARD ST. ELIZABETH'S MEDICAL CENTER OF BOSTON, INC., *Defendants*.	Case No. 18-cv-11160-WGY **ORAL ARGUMENT REQUESTED**

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS THE UNITED STATES' COMPLAINT-IN-INTERVENTION

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Defendants Steward Health Care System LLC ("Steward"), Steward Medical Group, Inc. ("SMG"), and Steward Saint Elizabeth's Medical Center of Boston, Inc. ("SEMC"), respectively submit this memorandum of law in support of their Fed. R. Civ. P. 12(b)(6) motion to dismiss.

INTRODUCTION

The government's Complaint-in-Intervention (Dkt. 52, "Complaint" or "Compl.") seeks to expand liability under the Stark Law far beyond what the statute and its implementing regulations authorize. The Complaint alleges that every Medicare claim for inpatient or outpatient hospital services resulting from procedures performed by Dr. Arvind Agnihotri at SEMC was fraudulent under the False Claims Act ("FCA"), simply because (1) Dr. Agnihotri's compensation varied with the number of surgeries he performed (which the government, in marked understatement, concedes is "not unusual," Compl. ¶ 112 n.20); and (2) his aggregate compensation was in the 90th percentile for cardiac surgeons in the Eastern United States (which, by definition, is true of 10% of all such doctors). Those allegations could be made of many surgeons in Boston, a city with one of the highest costs of living in the United States and some of the best hospitals in the world. Yet after more than five years of investigating a sprawling qui tam complaint against Defendants, that is all the government could come up with. Unless this Court dismisses the Complaint, it will open the floodgates to qui tam suits against any hospital that compensates its surgeons in part based on their productivity measured by the number of surgeries they perform, even where, as here, there is no allegation that a single surgery was unnecessary, improperly performed, or overbilled.

The Stark Law and FCA were not intended for this. The Stark Law, which, in certain circumstances, prohibits hospitals from billing Medicare for hospital services referred by a physician on the hospital's payroll, protects patients from "unnecessary overutilization of services or increased costs." *Id.* ¶ 2. The FCA exists "to recover monies that were obtained from the government by fraudulent misrepresentations." *U.S. ex rel. Escobar v. Universal Health Servs.,*

Inc., 842 F.3d 103, 106 (1st Cir. 2016). But the government does not allege that Dr. Agnihotri caused any unnecessary overutilization of services or subjected the government to any increased costs. It instead seeks to penalize Defendants, with trebled disgorgement, plus statutory penalties, for paying a world-class surgeon an amount commensurate with his talent, reputation, and productivity, in order to obtain the best possible services for their patients.

The government fails to plausibly allege its FCA claims. There is no false claim because paying an exceptionally qualified surgeon compensation tailored to his talents and the number of surgeries he performs does not violate the Stark Law. To satisfy the Stark Law, the government must plausibly allege, with specificity under Rule 9(b), *both* that Dr. Agnihotri's compensation (1) "took into account the volume or value of his referrals to" the hospital where he worked full-time as Chief of Cardiac Surgery; and (2) "exceeded fair market value." Compl. ¶ 92. Its allegations that Dr. Agnihotri was paid based in part on the number of surgeries he performed and was compensated in the 90th percentile fail to satisfy either required element. If they did, many leading hospitals would be exposed to FCA liability. The government also fails adequately to allege that any of the purported Stark Law violations were material to its decision to pay any claims, or that Defendants' purported violations of the Stark Law were knowing or reckless, as the FCA requires. Finally, the government cannot assert its equitable unjust enrichment and payment by mistake claims because the FCA provides it with an adequate, though unviable, remedy at law.

The Complaint should, for all these reasons, be dismissed with prejudice.

BACKGROUND

A. Steward's Recruitment Of Dr. Agnihotri

Steward is an integrated network that provides healthcare services nationwide. Compl. ¶¶ 17-18. Its network includes two wholly-owned subsidiaries: SMG, which "employs physicians that provide medical and administrative services and work in Massachusetts," and SEMC, a

Brighton hospital. *Id.* ¶¶ 19-20. SMG assigns physicians to work at Steward facilities like SEMC, and those facilities then pay SMG to cover a portion of the physicians' salaries. *Id.* ¶¶ 85-90.

In 2012, Steward's President and CEO recruited Dr. Arvind Agnihotri, a prominent cardiac surgeon, to join Steward as a full-time physician because Steward "wanted him to grow the Cardiac Surgery program at SEMC." *Id.* ¶ 58. Dr. Agnihotri's employment agreement with SMG provided that he would serve as SEMC's Chief of Cardiac Surgery. *Id.* ¶¶ 20, 63; Dkt. 53-2 at 14, 25. Dr. Agnihotri served in that role until March 31, 2022. Compl. ¶ 63.

B. Dr. Agnihotri's Improvements To SEMC's Cardiac Surgery Division

After Dr. Agnihotri became SEMC's Chief of Cardiac Surgery, SEMC saw a dramatic improvement to its cardiac surgery program and its ability to serve the local Brighton community: Before Dr. Agnihotri joined SEMC, SEMC's Division of Cardiac Surgery (the "Division") performed only 180 to 200 surgeries per year. *Id.* ¶ 58. "Within two years of Dr. Agnihotri starting at SEMC," the Division had more than doubled its surgical volume. *Id.* ¶¶ 108, 119.

The government has ***not*** alleged that, at any point under Dr. Agnihotri's leadership, Dr. Agnihotri or his colleagues in the Division performed medically unnecessary procedures, provided poor quality of care, or otherwise overbilled the government. Nor has it alleged that Dr. Agnihotri failed to perform his clinical or administrative duties. To the contrary, it alleges that Dr. Agnihotri personally performed more than his fair share of surgeries. *Id.* ¶¶ 108, 116; Dkt. 52-9.

C. Dr. Agnihotri's Compensation And The Stark Law

At various points between 2012 to 2022, Dr. Agnihotri received a signing bonus, base salary for clinical and administrative services, "quality" bonuses that paid more if the Division met performance metrics, and "incentive compensation." Compl. ¶ 66. This case turns on whether Dr. Agnihotri's compensation was unlawful under the Stark Law, 42 U.S.C. § 1395nn, which (among other things) forbids physicians from referring "designated health services" to facilities with which

they have certain compensation arrangements. The government alleges that Dr. Agnihotri had a forbidden compensation arrangement with SEMC because of the way SMG calculated his productivity bonus and the total amount of his compensation.

Productivity Bonus: Dr. Agnihotri worked full-time at SEMC and performed all his surgeries there. Compl. ¶ 63. Each surgery he performed in a SEMC operating room generated a professional services fee for him and a facility fee for SEMC. *Id.* ¶¶ 44, 70. His employment contract with SMG entitled him to a productivity bonus based in part on the number of these surgeries that he performed. *Id.* ¶ 69. Because the Stark Law deems a surgeon's use of a hospital's facilities to be a "referral" of "designated health services" to the hospital, the government alleges that Dr. Agnihotri's productivity bonus implicitly compensated him for these "referrals," rather than for his work in performing the surgeries that necessitated them. *Id.* ¶¶ 68, 70-71.

The government concedes that "[it] is not unusual in the hospital industry to determine productivity bonuses for physicians based on the physician's personally performed wRVUs [work relative value units]." *Id.* ¶ 112 n.20. "wRVUs represent the relative amount of physician work, resources, and expertise necessary to provide a service to a patient . . . ." *Id.* Dr. Agnihotri's bonus was not based on wRVUs but rather, given his leadership role and his mandate to grow the Division, on the "the number of surgical cardiovascular cases performed" by the "Division . . . each year," including by him. *Id.* ¶¶ 69, 73-74, 78, 81. His contract defined a "surgical cardiovascular case" as "any surgical cardiac procedure performed by the Division . . . involving the use of an operating room." *Id.* ¶ 69. The government does not explain why "a surgical cardiac procedure . . . involving the use of an operating room" is meaningfully different from wRVUs when measuring the amount of physician work, resources, and expertise that a service entails.

Total Compensation: The government alleges that at least in 2014, 2016, and 2017, Dr.

Agnihotri's aggregate compensation "exceeded the ninetieth percentile for cardiovascular surgeons based in the eastern region of the United States based on" an industry group's benchmarking statistics. *Id.* ¶¶ 99-102. Defendants purportedly did not perform an analysis to determine if Dr. Agnihotri's compensation was fair market value. *Id.* ¶ 82. The government alleges that Defendants' internal policies required them to provide a "written explanation" when a physician's "compensation exceeds the 75th [percent]ile" of this benchmark, but that Defendants did not do this for Dr. Agnihotri. *Id.* ¶¶ 98-99. Finally, the government alleges that certain SEMC employees expressed concerns that Dr. Agnihotri was paid "a set amount per surgery," not per wRVU, and was otherwise "overcompensated." *Id.* ¶¶ 150, 153-54.

LEGAL STANDARD

To survive dismissal under Fed. R. Civ. P. 12(b)(6), a complaint must "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "Where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief'" under Fed. R. Civ. P. 8(a). *Maldonado v. Fontanes*, 568 F.3d 263, 268 (1st Cir. 2009) (citation omitted).

FCA claims must satisfy Rule 9(b)'s heightened pleading standard, *e.g.*, *U.S. ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009), which means "[t]here must be particularized allegations of claims for payment arising from that scheme. . . . And under Rule 9(b), those claims [and the fraud itself] must be described with some level of specificity." *U.S. ex rel. Flanagan v. Fresenius Med. Care Holdings, Inc.*, 2022 WL 17417577, at *17 (D. Mass. Dec. 5, 2022); *see, e.g.*, *U.S. ex rel. Kelly v. Novartis Pharms. Corp.*, 827 F.3d 5, 14 (1st Cir. 2016) (requiring that the "who, what, where, and when of the" underlying fraudulent scheme be pleaded with specificity) (quotation marks omitted). This entails pleading, among other things, "specific medical providers who allegedly submitted false claims, the rough time periods, locations, and amounts of the

claims," and "the specific government programs to which the claims were made. Merely alleging that a scheme was wide-ranging—and, therefore, that a fraudulent claim was presumably submitted—will not suffice. Nor is evidence of illegal conduct alone sufficient to state an FCA claim." *Kelly*, 827 F.3d at 13-14 (quotation marks omitted). These same particularity requirements apply to unjust enrichment and payment by "mistake." Fed. R. Civ. P. 9(b); *see N. Am. Cath. Educ. Programming Found., Inc. v. Cardinale*, 567 F.3d 8, 15 (1st Cir. 2009) (Rule 9(b) "cover[s] associated claims where the core allegations effectively charge fraud").

ARGUMENT

The government wrongly alleges that Defendants' submission of Medicare claims resulting from Dr. Agnihotri's referrals violates the FCA (Counts I & II), 31 U.S.C. §§ 3729(a)(1)(A)-(B), and gives rise to common law unjust enrichment and payment by mistake claims (Counts III & IV). This Court should dismiss all four Counts with prejudice.

I. THE GOVERNMENT FAILS ADEQUATELY TO ALLEGE ITS FCA COUNTS (I & II).

The FCA "provides for civil liability for anyone who 'knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval' or 'knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.'" *Flanagan*, 2022 WL 17417577, at *6 (quoting 31 U.S.C. § 3729(a)(1)(A)-(B)). Counts I and II should be dismissed because the government fails plausibly to allege three central elements of an FCA violation under Section 3729(a)(1): (A) a false claim, (B) material to the government's decision to pay, (C) that Defendants knew was false.

A. The Government Does Not Allege A Stark Law Violation.

The government alleges that Defendants submitted claims to Medicare that were false because Defendants certified their compliance with the Stark Law but had, in fact, allegedly

violated the Stark Law. Compl. ¶ 168. The Stark Law (or "Self-Referral Law") prohibits a healthcare entity from billing Medicare when a physician makes a referral for "designated health services" if the referring physician has a "financial relationship" with the healthcare entity and no Stark Law exception applies. 42 U.S.C. § 1395nn(a). The FCA and common law claims in the Complaint are predicated entirely on an alleged Stark violation.

To plead a Stark Law violation, the government must allege: (1) a physician's "referral to [a healthcare] entity for the furnishing of designated health services" ("DHS"), (2) a "direct" or "indirect" compensation relationship between the physician and the healthcare entity, and (3) that the healthcare entity presented or caused to be presented a claim for reimbursement for DHS furnished pursuant to that physician's referral. 42 U.S.C § 1395nn(a)(1)-(2), (h)(1); 42 C.F.R. §§ 411.353(a)-(b), 411.354(a)(ii) & (c) (2020). The Stark Law also has safe harbors or exceptions for compensation arrangements that do not violate the statute if certain conditions are met. *See* 42 U.S.C. § 1395nn(3); 42 C.F.R. § 411.357 (2020). An FCA complaint predicated on a purported Stark Law violation must "allege[] conduct that plausibly would have *violated* the . . . Stark [Law], including negation of safe harbors, in order to make a supported allegation that the claims induced by the alleged conduct were false under the FCA." *U.S. ex rel. Witkin v. Medtronic, Inc.*, 189 F. Supp. 3d 259, 268 n.3 (D. Mass. 2016).

The government fails to plausibly allege a Stark Law violation for two reasons. *First*, the government does not plead that there was a direct compensation arrangement (Compl. ¶ 4) and does not plausibly allege that there was an "indirect compensation relationship" within the meaning of the Stark Law. *Second*, the government tries but fails to show that the indirect compensation relationship's safe harbor requirements were not met.

1. There Was No Indirect Compensation Relationship.

The government's Stark Law theory hinges on its allegation that "SEMC had an indirect

compensation arrangement with Dr. Agnihotri." *Id.* ¶ 4. The government acknowledges that it can establish an indirect compensation arrangement only if it pleads, among other things, that "(1) there was an unbroken chain of financial relationships between the referring physician and the entity furnishing designated health services ('DHS entity'); (2) the referring physician received aggregate compensation from the person or entity in the chain with which the physician had a direct financial relationship that varied with, or took into account, the volume or value of the physician's referrals to the DHS entity or other business generated by the referring physician for the DHS entity[1]; and (3) the DHS entity had knowledge that the referring physician received aggregate compensation that varied with, or took into account, the volume or value of referrals or other business generated by the referring physician." *Id.* ¶ 33; 42 C.F.R. § 411.354(c)(2)(i)-(iii) (2020) (footnote added). At a minimum, the government fails to allege the second and third elements of an indirect compensation arrangement.

Volume/Value: The government fails adequately to allege that Dr. Agnihotri's compensation from SMG "varie[d] with the volume or value of [his] referrals" of DHS to SEMC. 42 C.F.R. § 411.354(c)(2)(ii) (2020). Dr. Agnihotri made a "referral" to SEMC of "inpatient [or] outpatient hospital services" each time he performed a surgery at SEMC that involved the use of hospital services. *Id.* § 411.351. Inpatient and outpatient hospital services are DHS. *Id.* But Dr. Agnihotri's "professional services" in performing the surgeries were not DHS. *Id.* Dr. Agnihotri's compensation thus "varie[d] with the volume or value of his referrals" of DHS to SEMC only if he received the bonus for making the referrals rather than for performing the surgeries.

The government's theory of liability depends on an interpretation of the phrase "varies with

[1] "Other business generated" refers to payments from payors other than Medicare, but the government does not allege that claims were submitted to other payors, Compl. ¶¶ 2, 33 n.4.

the volume or value of referrals" that has been rejected by the Centers for Medicare & Medicaid Services ("CMS"), the agency that wrote the Stark Law's regulations and is responsible for interpreting them. The government's interpretation is essentially this: if a surgeon's pay depends on the number of surgeries he personally performs, and his performance of those surgeries results in a facility fee for the hospital where he performs them, his pay *necessarily* "varies with the volume or value of [his] referrals" of DHS to the hospital in violation of the Stark Law. *E.g.*, Compl. ¶ 105 ("Dr. Agnihotri was eligible for incentive compensation which varied based on the volume of his Surgical Cardiovascular Cases and, thus, was determined in a manner that took into account the volume or value of his referrals . . . .").

CMS has expressly recognized that this understanding of the Stark Law is overbroad and would result in the imposition of liability that Congress did not intend and that would not serve the Stark Law's core purposes. Accordingly, it has determined that "a productivity bonus will not take into account the volume or value of the physician's referrals solely because corresponding hospital services (that is, designated health services) are billed each time the employed physician personally performs a service." 85 Fed. Reg. 77492, 77539 (Dec. 2, 2020). Put another way, "[a]n association between personally performed physician services and designated health services furnished by an entity does not convert compensation tied solely to the physician's personal productivity into compensation that takes into account the volume or value of a physician's referrals to the entity or the volume or value of other business generated by the physician for the entity." *Id.* "This is true whether the compensation arrangement is . . . directly between an entity and a physician or is an indirect compensation arrangement." *Id.* CMS's interpretation of its own regulations is entitled to deference. *E.g.*, *Barnhart v. Walton*, 535 U.S. 212, 217 (2002) ("Courts grant an agency's interpretation of its own regulations considerable legal leeway.").

CMS's interpretation is consistent with Congress's decision to permit physicians to earn productivity bonuses; the government's theory is not. If the government's theory were correct, no hospital could ever compensate a physician based on the number of surgeries the surgeon performed in an operating room because all such surgeries necessarily involve a referral of "inpatient or outpatient medical services" to the hospital. But Congress expressly recognized in the "bona fide employment" safe harbor that "a productivity bonus based on services performed personally by the physician" does not run afoul of the "volume or value" test merely because those services result in referrals of DHS to the entity paying the bonus. 42 U.S.C. § 1395nn(e)(2).

The government's theory also would impose the Stark Law's draconian penalties on commonplace financial arrangements that, like Dr. Agnihotri's, pose no threat of "unnecessary overutilization of services or increased costs." Compl. ¶ 2. The Stark Law is a complex, technical, strict-liability statute that can result in a hospital being denied payment, and charged per-claim fines, for every single claim it submits to Medicare that is linked to a prohibited financial arrangement—even if, say, $20 million of claims are linked to a $5,000 consulting agreement. *See* 66 Fed. Reg. 856, 860 (Jan. 4, 2001). Accordingly, CMS has emphasized the need "to interpret the [Stark Law's] prohibitions narrowly and the exceptions broadly." *Id.*; *see also* 69 Fed. Reg. 16054, 16056 (March 26, 2004) ("[W]e have attempted to preserve the [Stark Law's] core statutory prohibition while providing sufficient flexibility to minimize the impact of the rule on many common business arrangements."). The government's attempt to expand the definition of the phrase "varies with the volume or value of referrals" in the context of productivity-bonus provisions like Dr. Agnihotri's is an overreach that ignores Congress's decision to permit such agreements and CMS's guidance about the intended meaning of that phrase.

The government strains to avoid the weight of legal authority against it by noting that Dr.

Agnihotri's productivity bonus was based on the volume of "surgical cardiac cases" he performed rather than on the volume of "wRVUs" those procedures entailed, Compl. ¶112, but that fact is immaterial to the proper interpretation of the phrase "varies with . . . the volume or value of referrals" in 42 C.F.R. § 411.354(c)(2)(ii) (2020). "Surgical cardiac cases" and "wRVUs" are both terms that describe physicians' professional services. And both may, depending on the procedure involved, necessitate a corresponding referral of DHS. Even so, the government argues that a productivity bonus based on "surgical cardiac cases" as defined in Dr. Agnihotri's contract varies with the volume or value of DHS referrals because those procedures necessitate a referral of DHS, while a productivity bonus based on a "physician's personally performed wRVUs" *does not* "take into account the volume or value of [DHS] referrals" *even if* the performance of those wRVUs necessitates a referral of DHS. *See* Compl. ¶ 112 n.20. That argument is unsupported and unsupportable. It flies in the face of CMS's guidance that the Stark Law's prohibitions should be interpreted narrowly and flexibly so as not to penalize business arrangements that do not implicate its core concerns.

If anything, Dr. Agnihotri's compensation arrangement was *less likely* to implicate Stark Law concerns than a wRVU compensation arrangement. wRVus turn on the "work" and "resources" needed, *id.*, so wRVU-based bonuses may incentivize doctors to recommend unnecessarily complex surgeries. Simone Betchen, *Surgery needs a new pay model, free from incentives to do more procedures*, STAT (Sept. 19, 2022), https://tinyurl.com/mw5v6m66. Dr. Agnihotri's compensation removed this incentive.

In short, the government has not plausibly alleged that Dr. Agnihotri's contract rewarded him for making referrals rather than for performing surgeries. The contract's language is plain: it rewards Dr. Agnihotri for "procedure[s]," not referrals. Compl. ¶ 69. The contract does not entitle

Dr. Agnihotri to bonus compensation for making DHS referrals unconnected to performing his own professional services. It also does not make his bonus depend on the value of any DHS referrals necessitated by him performing professional services. The government is therefore forced to rely on the fact that Dr. Agnihotri's performance of cardiac surgeries at SEMC necessitated a referral of DHS to SEMC, coupled with allegations that Defendants anticipated that, wanted that, were motivated by that, and were pleased by that. *E.g.*, *id.* ¶ 114. Even assuming the truth of those allegations (which Defendants dispute), they are not enough to satisfy the government's pleading burden. The mere fact that personally performed services correspond with DHS referrals is not enough to show that a productivity bonus based on those services "varies with the volume or value" of the referrals, and Defendants' feelings about such a correspondence are irrelevant.

Finally, the government's other allegations on this issue are also deficient. It alleges that Dr. Agnihotri's incentive compensation took into account "Surgical Cardiovascular Cases referred to SEMC by other physicians in the Division and performed by the other physicians in the Division." Compl. ¶ 72. But Dr. Agnihotri did not make those referrals, and the government does not base its theory of liability on those referrals. The government also alleges that "Dr. Agnihotri only received incentive compensation for the Division's Surgical Cardiovascular Cases at SEMC." *Id.* But that is the hospital where Dr. Agnihotri worked full-time, and the Stark Law does not prohibit doctors from performing surgeries at their place of employment. Nor does CMS "consider the volume or value standard implicated by otherwise acceptable compensation arrangements for physician services solely because the arrangement requires the physician to refer to a particular provider as a condition of payment." 66 Fed. Reg. 856, 877 (Jan. 4, 2001).

Knowledge: The indirect compensation relationship's third element—knowledge that compensation varied with the value or volume of referrals—is not met for the reasons stated below

in the section that addresses the FCA's scienter requirements. *Infra*, Part I.C. The government fails plausibly to address this required element of a Stark Law violation as well.

2. In Any Event, A Stark Law Safe Harbor Applies.

Even if the government had plausibly alleged an indirect compensation relationship, it fails to allege facts that "negat[e]" the safe harbor for such relationships, *Medtronic*, 189 F. Supp. 3d at 268 n.3, despite expressly taking on this burden, *e.g.*, Compl. ¶ 7 (alleging that Defendants' "indirect compensation arrangement failed to satisfy the requirements of an applicable exception to the Stark Law"); *see id.* ¶¶ 93-120 (devoting 28 paragraphs to this issue). Pursuant to the safe harbor established by 42 C.F.R. § 411.357(p) (2020), an "indirect compensation arrangement" does not violate the Stark Law if (1) the physician's compensation "is fair market value for services and items actually provided," (2) it is "not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician"; and (3) "[t]he compensation arrangement . . . is set out in writing, signed by the parties, and specifies the services covered by the arrangement."[2] As noted, the government implicitly admits it must plead facts negating this safe harbor, Compl. ¶¶ 93-120, but it fails to do so.

FMV: The government fails adequately to allege that Dr. Agnihotri's compensation exceeded "the fair market value for [his] services." 42 C.F.R. § 411.357(p)(1)(i) (2020). Fair market value ("FMV") means "[t]he value in an arm's-length transaction, consistent with the general market value," meaning "the compensation that would be paid at the time the parties enter into the service arrangement as the result of *bona fide* bargaining between well-informed parties that are not otherwise in a position to generate business for each other." *Id.* § 411.351. Dr.

[2] In 2021, CMS added additional requirements "[i]f remuneration to the physician is conditioned on the physician's referrals to a particular provider," *id.* § 357(p)(4), but Dr. Agnihotri's contract had no such conditions at the time, Dkt. 52-4 at 2, so those additional requirements are irrelevant.

Agnihotri's compensation was FMV because he negotiated his contract in an arm's-length transaction with Defendants. Compl. ¶¶ 59-62, 75-79. That fact alone shows that his compensation was FMV.[3]

Ignoring the regulatory definition, the government alleges simply that Dr. Agnihotri's compensation "exceeded the ninetieth percentile for cardiovascular surgeons . . . in the eastern region of the United States" based on benchmarking provided by a medical industry organization, Compl. ¶¶ 97, 99, but that allegation does not satisfy its pleading burden. CMS has cautioned that consulting "salary schedules" is only a "starting point" in the FMV analysis, and "[p]arties do not necessarily fail to satisfy the fair market value requirement simply because the compensation exceeds a particular percentile in a salary schedule." 85 Fed. Reg. 77492, 77557 (2020). Courts have endorsed CMS's view that fair market value is defined as the result of an arm's-length negotiating process and cannot be established by resort to a simplistic percentile test. *U.S. ex rel. Villafane v. Solinger*, 543 F. Supp. 2d 678, 691 n.13 (W.D. Ky. 2008). The government, despite having had over five years to investigate, makes no particularized FMV allegations showing that Dr. Agnihotri was overpaid, and thus fails to meet Rule 9(b)' requirements.

If anything, the government's allegations suggest that Dr. Agnihotri's compensation is consistent with "an arm's-length transaction," 42 C.F.R. § 411.351. Some of Dr. Agnihotri's compensation stems from a large signing bonus, Compl. ¶¶ 66, 95, a necessary inducement for a surgeon of Dr. Agnihotri's caliber to join a then-small cardiac surgery practice, *see id.* ¶ 58, competing against hospitals like Mass General Brigham and Beth Israel. Dr. Agnihotri received

[3] The government speculates on "information and belief" that one of the two executives who recruited Dr. Agnihotri was "friends" with him. Compl. ¶ 59. This allegation lacks "particularity," does not "set forth the facts on which the belief is founded," and does not allege a lack of an arm's-length transaction. *U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 226 n.8 (1st Cir. 2004), *abrog. on other grounds*, *Allison Eng. Co. v. U.S. ex rel. Sanders*, 553 U.S. 662 (2008).

significant incentive compensation because he performed hundreds of surgeries each year, doubling the Division's surgeries within two years of joining. *Id.* ¶¶ 69, 73-74, 78, 81, 119. Presumably, no more than 10% of cardiac surgeons could accomplish the same result. *See Villafane*, 543 F. Supp. 2d at 691-92 (finding that similar "consistently above the 90th percentile" allegations were "unremarkable" given physician's experience and range of clinical and administrative responsibilities). Dr. Agnihotri was also Chief of Cardiac Surgery and paid to perform corresponding "administrative duties," Compl. ¶ 66 n.8, so "comparing" him "to an 'ordinary'" cardiac surgeon "is to compare 'apples and oranges,'" *Villafane*, 543 F. Supp. 2d at 692. Finally, Boston has a higher cost of living than most of the Eastern United States. *See* 66 Fed. Reg. 856, 916 (Jan. 4, 2001) (assessing FMV by considering "similar environments").

The government's remaining FMV allegations are unpersuasive and conclusory. It alleges that Defendants performed no FMV "analysis" of Dr. Agnihotri's compensation and, in purported violation of internal guidance, failed to "document a written explanation justifying Dr. Agnihotri receiving compensation in excess of the seventy-fifth percentile." *Id.* ¶¶ 82, 99. These allegations, even if true, do not plausibly allege that Dr. Agnihotri's compensation ***actually exceeded FMV***. The government alleges that Dr. Agnihotri's compensation "could not possibly be fair market value" because it reflected surgeries performed by the rest of the Division. *Id.* ¶ 96. The government does not justify this implausible inference. As a matter of "common sense," *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009), companies often compensate managers for their divisions' performance. Last, it alleges that Dr. Agnihotri's incentive compensation "was not calculated based on his professional services, personal productivity, or [wRVUs]." Compl. ¶ 112. But it conspicuously does not allege that these compensation methods would have yielded a lower income.

The government fails adequately to allege that Dr. Agnihotri's compensation exceeded FMV and thus fails to negate the first of the safe harbor's requirements.

Volume/Value: Again, *supra*, pp. 8-12, the government fails adequately to allege that Dr. Agnihotri's compensation was "determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS," 42 C.F.R. § 411.357(p)(1). It thus also fails to negate the safe harbor's second requirement.

Contract In Writing: The government does not dispute that Dr. Agnihotri's "compensation arrangement . . . is set out in writing, signed by the parties, and specifies the services covered by the arrangement." 42 C.F.R. § 411.357(p)(2). Indeed, the government attaches those compensation agreements as exhibits to its Complaint. *See* Dkts. 52-2 to 52-6.

The government's failure to negate the applicability of this safe harbor means there is no Stark Law violation and thus no false claim.

B. The Government Does Not Allege Materiality.

The government fails to "sufficiently allege[] that the regulatory violations in question were material to the government's payment decision, a requirement for an actionable FCA claim." *Escobar*, 842 F.3d at 105. This is a "rigorous," "demanding" standard; the FCA does not penalize "garden-variety . . . regulatory violations." *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 192, 194 (2016). Materiality turns on (1) whether compliance is a condition of payment; (2) whether the violation goes to the "essence of the bargain'" or is "minor or insubstantial"; and (3) whether the government "consistently refuses to pay claims" when it has knowledge of similar violations. *Escobar*, 842 F.3d at 110 (quoting *Escobar*, 579 U.S. at 195) (quotation marks omitted). The government fails adequately to allege any of these three elements.

First, the government alleges that "Medicare conditioned payment on compliance with the Stark Law," Compl. ¶ 124, but nothing more. This allegation does not establish materiality on its

own. *See Escobar*, 579 U.S. at 194 ("A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment.").

Second, the government does not allege Stark Law violations that go to the "essence of the bargain." As noted, the government concedes that Dr. Agnihotri's compensation would have posed no Stark Law concerns had it compensated him based on wRVUs rather than surgical procedures. Compl. ¶ 112 n.20. Even if Dr. Agnihotri's compensation arrangement technically violated the Stark Law (and it did not), the government does not allege that this was anything more than a "minor or insubstantial" violation, *Escobar*, 842 F.3d at 110, as there was no "unnecessary overutilization of services and increased costs," *i.e.*, core Stark Law misconduct. Compl. ¶ 2.

Third, the government alleges that it "routinely pursues or settles cases, like this one, alleging that entities and individuals submitted or caused the submission of claims that were false because they violated the Stark Law." *Id.* ¶ 177. But it cites only Department of Justice enforcement decisions, not CMS payment decisions. *Id.* ¶¶ 178-84; *see United States v. Strock*, 982 F.3d 51, 63 (2d Cir. 2020) (explaining that "*Escobar* indirectly indicates that allegations of post hoc prosecutions or other enforcement actions do not carry the same probative weight as allegations of nonpayment" and "[a]llowing the government to rely on post hoc enforcement efforts to satisfy the materiality requirement would allow the government to engage in . . . materiality manufacturing"). The government also makes no effort to analogize the facts here to the cases it cites, nor could it, because in those cases, the Stark Law violations all resulted in medically unnecessary claims or directly tied compensation to referrals, unlike here.[4] Finally, and

[4] *See, e.g.*, *United States v. Rogan*, 517 F.3d 449, 451-52 (7th Cir. 2008) (conspiracy to file claims for medically unnecessary services and to compensate physicians for referrals, not physician

dispositive on this point, *the government does not allege that CMS stopped paying for claims resulting from Dr. Agnihotri's referrals at any point during the five-plus years the government spent investigating this Complaint*. This is hard proof that the alleged Stark Law violation here is not material to its decision to pay. In *U.S. ex rel. Hlywiak v. Great Lakes Educ. Loan Servs., Inc.*, 2022 WL 787957 (D.N.J. Mar. 15, 2022), the court ruled that when "the Government had knowledge" of a purported fraudulent scheme yet never "stopped making payments or refused to make payments after gaining such knowledge," "this fact seems to establish conclusively the lack of materiality." *Id.* at *11. So too here. The government thus fails to adequately allege materiality.

C. The Government Does Not Allege Scienter.

Finally, the government's FCA counts should be dismissed because they fail to allege that Defendants acted "knowingly." 31 U.S.C. §§ 3729(a)(1)(A)-(B). "[K]nowingly" under the FCA encompasses "actual knowledge," "deliberate ignorance," and "reckless disregard of the truth or falsity of the information." *Id.* § 3729(b). This element hinges on "subjective beliefs." *U.S. ex rel. Schutte v. SuperValu Inc.*, 143 S. Ct. 1391, 1399 (2023). The government must also allege that Defendants "knowingly violated a requirement that [they] know[] is material to the Government's payment decision." *Escobar*, 579 U.S. at 181. "Strict enforcement of the FCA's knowledge requirement helps to ensure that innocent mistakes made in the absence of binding

provision of services); *U.S. ex rel. Reilly v. North Broward Hospital District,* No. 10-cv-60590 (S.D. Fla.), Dkt. 75 (surgeons pressured to make referrals that compromised patient care); *U.S. ex rel. Felten v. William Beaumont Hosps.*, No. 2:10-cv-13440 (E.D. Mich.), Dkt. 1 (physicians paid for services they never provided); *United States ex rel. Payne v. Adventist Health System-Sunbelt, Inc.*, No. 12-cv-00856 (W.D.N.C.), Dkt. 6 (physicians overbilled for services not provided); *U.S. ex rel. Fischer v. Cmty. Health Network, Inc.*, No. 1:14-cv-1215 (S.D. Ind.), Dkt. 96 (hospital recruited dozens of physicians from local practices to lock-up their referrals and conditioned certain payments to these physicians on meeting target revenues); *U.S. ex rel. Longo v. Wheeling Hospital, Inc.*, No. 19-cv-00192 (W.D. Pa.), Dkt. 19 (hospital paid a non-employed physician based on the number of referrals to the hospital; and hospital paid employed physicians based on the net revenue attributable to each physician).

interpretive guidance are not converted into FCA liability . . . ." *U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 287 (D.C. Cir. 2015) (quotation marks omitted).

The government fails to plead scienter. It alleges that Defendants received Stark Law training. *E.g.*, Compl. ¶¶ 129-31. But it does not allege that Dr. Agnihotri's compensation arrangement so obviously violated the Stark Law's strictures (when similar, wRVU-based compensation would not) that anyone exposed to this training was reckless not to catch the (purported) violation. *See, e.g.*, *U.S. ex rel. Modglin v. DJO Glob. Inc.*, 48 F. Supp. 3d 1362, 1405 (C.D. Cal. 2014) (scienter not adequately alleged where "none of the[] allegations support[ed] an inference that [defendants] knew they could not lawfully seek reimbursement for the stimulators from Medicare or the other federal programs identified in the complaint"), *aff'd*, 678 F. App'x 594 (9th Cir. 2017). The government then alleges that Defendants did not follow their internal procedures requiring them to justify Dr. Agnihotri's compensation in writing. Compl. ¶¶ 82, 99. But it does not suggest that Defendants disregarded those policies to avoid learning that Dr. Agnihotri's compensation might be unlawful or material to CMS's willingness to pay. And a mere disregard of internal policies does not violate the FCA. *See U.S. ex rel. Clausen v. Lab'y Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002). Finally, the government alleges that some SEMC employees expressed concerns that Dr. Agnihotri was paid "a set amount per surgery," not per wRVU, and was otherwise "overcompensated." Compl. ¶¶ 150, 153-54. But it does not allege that any of them thought that Dr. Agnihotri's compensation was *illegal* or violated any part of the Stark Law's requirements. *See id.* ¶¶ 148-54. Executives can be concerned about an employee's compensation package without thinking that they are violating the law and defrauding Medicare. *Cf. U.S. ex rel. Hart v. McKesson Corp.*, — F.4th —, 2024 WL 1056936, at *10 (2d Cir. 2024) (rejecting scienter allegations in AKS context where the relator expressed compliance concerns to

a supervisor because "it suggests only that [the relator] believed" that the defendant was violating the law, not that anyone else did).

For all these reasons, this Court should dismiss Counts I & II of the Complaint.

II. THE GOVERNMENT FAILS ADEQUATELY TO ALLEGE ITS OTHER COUNTS (III & IV).

Counts III & IV allege unjust enrichment and payment by mistake. These claims are one and the same, not two different causes of action: "a "transfer induced by [an] invalidating mistake is subject to rescission and restitution," and "[t]he transferee is liable in restitution as necessary to avoid unjust enrichment." Restatement (Third) of Restitution and Unjust Enrichment § 5(1) (2011). These claims can thus be dismissed for the same two reasons. *First*, these claims depend on the same insufficiently pled Stark Law violations discussed above. *See* Compl. ¶ 204 ("By directly or indirectly obtaining from the United States, though Medicare, funds to which SEMC was *not entitled*, SEMC was unjustly enriched . . . .") (emphasis added); *id.* ¶ 208 (similar). Because there was no Stark Law violation, *supra*, Part I.A, these claims accordingly fail as well. *Second*, unjust enrichment and payment by mistake are equitable remedies, and thus are unavailable to the extent the government "has an adequate remedy at law." *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992). The government's unjust enrichment and payment by mistake claims should be dismissed because the FCA provides the government with an adequate remedy at law. *See United States v. Teva Pharms. USA, Inc.*, 560 F. Supp. 3d 412, 423-24 (D. Mass. 2021). The fact that the government's FCA claims should also be dismissed does not matter. "It is the availability of a remedy at law, not the viability of that remedy, that prohibits a claim for unjust enrichment." *Shaulis v. Nordstrom, Inc.*, 865 F.3d 1, 16 (1st Cir. 2017).

CONCLUSION

For all these reasons, the government's Complaint-In-Intervention should be dismissed.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on April 8, 2024, I electronically filed the above document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all counsel of record.

/s/ *William D. Weinreb*
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